UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,206	12/21/2001	Nisar Ahmed Khan	2183-5222US	5353

24247 7590 12/16/2004

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,206	KHAN ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I, claims 1-12 and 16-20, and the species of AQGV (Seq. ID 2) in the reply filed on July 22, 2004 is acknowledged.

2. Claims 1-1-7, 9-12 and 16-20 are generic to a plurality of disclosed patentably distinct species of inflammatory conditions comprising infection with pathogenic bacteria, infection with pathogenic viruses, infection with pathogenic fungi, infection with pathogenic protozoa, parasitic worm infection, bone disease, induction of weight loss, joint disease, inflammation of the skin and/or mucosal surfaces, hernias, heart infarcts, neonatal lung disease, and autoimmune disease. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Allen Turner on or about December 2, 2004, a provisional election was made with traverse to prosecute the species of

infection with pathogenic bacteria, specific to claim 8. Affirmation of this election must be made by applicant in replying to this Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-12 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite a method of treatment of an inflammatory condition comprising the administration of a molecule comprising an oligopeptide or functional analogue thereof. The molecule is required to be capable of reducing the production of NO by a cell. The species elected for the oligopeptide is the sequence of Seq ID #2 (AQGV) and the species elected for the condition is treatment of infection by pathogenic bacteria. The treatment of anthrax is specifically claimed.

First, the claims, given their broadest reasonable interpretation, are not limited to the administration of a peptide of defined sequence; all that is required is that the molecule comprises the peptide, i.e. that the sequence is found somewhere in the administered molecule. However, the only showing of the specification uses a molecule consisting of a specific peptide sequence as indicated in Table 6. It remains undisclosed in the specification and therefore not enabled as to how molecules containing the sequence are to be formulated, administered and how they will have their

effect. In what domains of a molecule may the claimed peptide be found and still have the desired effect? What locations will result in cleavage to liberate the oligopeptide sequence? All of these questions are critical to the successful practice of the claimed method; however, none of these questions are addressed in the specification. The specification provides no guidance other than a specific sequence but the claims must be interpreted more broadly. As a result, a practitioner would engage in an undue amount of experimentation without a reasonable expectation of success.

Further, the claims recite the treatment of infections by pathogenic bacteria with molecules that reduce the NO production in cells of the organism to be treated. Further limitations recite modulation of TNF-alpha as a result of the claimed treatment. Finally, the treatment of anthrax is specifically claimed.

Per Cui et al., in Am. J. Physiol. Regul. Integr. Comp. Physiol. 286: R699-R709, 2004, lethality as a result of the exposure of an organism to the LeTx (lethal) toxin produced by Bacillus anthracis (anthrax) clearly results in circulatory shock; however, there is no inflammatory cytokine release or nitric oxide release observed. The reference concludes that therapies that modulate inflammatory cytokines (such as TNF-alpha) and nitric oxide may be applicable to shock caused by LPS or other bacterial toxins, these therapies are not expected to be successful when dealing the anthrax LeTx. Similarly, Moayeri et al., in the Journal of Clinical Investigation 112(5): 670-682 (September 2003) indicates that B. anthracis lethal toxin kills through a TNF-alpha-independent, non-inflammatory mechanism. Applicants provide a showing only certain peptides in an LPS-sepsis-shock model; Applicants suggest that "Down-regulating TNf-

alpha itself is also particularly useful in septic-shock-like conditions that not only display increased TNF-alpha activity but display further release of other inflammatory compounds, such as NO. NO production is a central mediator of the vascular and inflammatory response. Our results show that inflammatory cells like macrophages stimulated with an inflammatory active compound such as LPS produce large amounts of NO. However, these cells co-stimulated with most of the NMPF peptides 5 (NMPF peptide 1 to 14, 43 to 66 and 69), even in a very low dose (1 pg/ml), inhibited production of NO. Typical septic-shock-like conditions that can preferably be treated by down-regulating TNF-alpha and NO production comprise disease conditions such as those caused by Bacillus anthracis and Yersinia pestis toxins or infections with these micro-organisms likely involved in bio-terrorism. Anthrax toxin is produced by Bacillus anthracis, the causative agent of anthrax, and is responsible for the major symptoms of the disease." Applicants further state, in reference to changes in the peptide sequence, "We conclude, that the change in even one amino acid by a neutral amino acid can lead to different activity." The clear unpredictability in the art of anthrax treatment as evidenced by the cited documents, and in the absence of a predictable model of anthrax treatment, Applicants' showing is insufficient to provide enablement for the treatment of any pathogenic bacterial infection, particularly anthrax, with any molecule that comprises the claimed and elected peptide sequence.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-7, 10-11, 16-18 and 20 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by U.S. Patent 6,150,500 to Salerno

The patent teaches peptides administered (either individually or as two or more) to treat inflammatory conditions and specifically pathogenic bacterial infections leading to sepsis. The peptides reduce the NO production by cells surrounding the pathogenic bacterial infections. Non-disclosed effects such as gene regulation and TNF-alpha modulation are deemed inherent in the disclosure of the reference since the ultimate result of the treatment and the known modulation effects are the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651